<table>
<thead>
<tr>
<th>AWARD NUMBER:</th>
<th>W81XWH-14-1-0272</th>
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<tbody>
<tr>
<td>TITLE:</td>
<td>Improving universal suicide prevention screening in primary care by reducing false negatives</td>
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<tr>
<td>PRINCIPAL INVESTIGATOR:</td>
<td>Craig J. Bryan, PsyD, ABPP</td>
</tr>
<tr>
<td>CONTRACTING ORGANIZATION:</td>
<td>University of Utah 201 President Circle Rm 406 Salt Lake City, UT 84112</td>
</tr>
<tr>
<td>REPORT DATE:</td>
<td>September 2016</td>
</tr>
<tr>
<td>TYPE OF REPORT:</td>
<td>Annual</td>
</tr>
<tr>
<td>PREPARED FOR:</td>
<td>U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012</td>
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</tbody>
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**Title and Subtitle:** Improving universal suicide prevention screening in primary care by reducing false negatives

**Authors:** Craig Bryan, PsyD, ABPP

E-Mail: craig.bryan@utah.edu

**Performing Organization:**
University of Utah
201 President Circle Rm
406 Salt Lake City, UT
84112

**Sponsoring Agency:**
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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**Abstract:**
The primary aim of the proposed project is to develop a shortened version of the Suicide Cognitions Scale (SCS) and to evaluate its efficacy as a universal suicide prevention screen for use in military primary care clinics. We propose to achieve this aim by accomplishing the following objectives: (a) to develop a brief alert algorithm that can be used by primary care providers to accurately identify high-risk patients; (b) to improve the accuracy of universal suicide prevention screening methods by reducing false negative rates; and (c) to systematically quantify false negative rates across various patient subgroups (e.g., gender, race, age, deployment history, etc.) to identify those patient subgroups for whom the screening algorithm is most useful and accurate. Data collection is still in progress. There are no research findings to report at this time.
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1. Introduction

The primary aim of the proposed project is to develop a shortened version of the Suicide Cognitions Scale (SCS) and to evaluate its efficacy as a universal suicide prevention screen for use in military primary care clinics. We propose to achieve this aim by accomplishing the following objectives: (a) to develop a brief alert algorithm that can be used by primary care providers to accurately identify high-risk patients; (b) to improve the accuracy of universal suicide prevention screening methods by reducing false negative rates; and (c) to systematically quantify false negative rates across various patient subgroups (e.g., gender, race, age, deployment history, etc.) to identify those patient subgroups for whom the screening algorithm is most useful and accurate.

2. Keywords

Suicide prevention, primary care, suicide screening

3. Accomplishments

3.1. What were the major goals of the project?

<table>
<thead>
<tr>
<th>Task 1: Obtain IRB approvals</th>
</tr>
</thead>
<tbody>
<tr>
<td>1a. Initiate IRB proposals (months 1-3)</td>
</tr>
<tr>
<td>1b. Complete quarterly and annual reports to all IRBs (months 1-48)</td>
</tr>
<tr>
<td>1c. Complete final report to IRB (month 48)</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Task 2: Hire and train staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>2a. Hire and train research manager at University of Utah (months 1-3)</td>
</tr>
<tr>
<td>2b. Hire and train site evaluators (months 6-20)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Task 3: Begin and complete baseline data collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>3a. Begin enrollment and baseline data collection (months 12-26)</td>
</tr>
<tr>
<td>3b. Continue baseline data collection (months 13-42)</td>
</tr>
<tr>
<td>3c. Complete baseline data collection (month 42)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Task 4: Begin and complete longitudinal tracking and follow-up assessments</th>
</tr>
</thead>
<tbody>
<tr>
<td>4a. Begin longitudinal tracking and follow-up assessments (month 18)</td>
</tr>
<tr>
<td>4b. Continue longitudinal tracking and follow-up assessments (months 19-48)</td>
</tr>
<tr>
<td>4c. Complete longitudinal tracking and follow-up assessments (month 48)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Task 5: Data analysis, manuscript writing, report writing</th>
</tr>
</thead>
<tbody>
<tr>
<td>5a. Complete data analyses (months 26-48)</td>
</tr>
<tr>
<td>5b. Manuscript and report writing (months 28-48)</td>
</tr>
</tbody>
</table>

Completion of tasks:

1a. 100%
1b. 50%
1c. Not yet started
2a. 100%
2b. 100%
3a. Ongoing
3b. Ongoing
3c. Ongoing
4a. Ongoing
4b. Ongoing
4c. Not yet started
5a. Not yet started
5b. Not yet started
3.2. What was accomplished under these goals?

**Major activities:**

1. IRB amendment procedures initiated through NHRC and HRPO for each research site added, in addition to meeting site-specific IRB requirements and submitted required paperwork.
2. Site evaluator identified at Portsmouth Naval Medical Center (CDR Cunningham) and research assistant (Logan Smith) hired and trained to begin study recruitment and data collection. Received IRB approval to add Portsmouth Naval Medical Center on 07-MAR-2016.
3. Received commander support from McConnell AFB and Fort Carson as additional research sites; submitted IRB amendment to add both sites to study. Received IRB approval to add both sites on 06-JAN-2016.
4. Conducted interviews to hire research assistant for on-site recruitment at Fort Carson (15-JULY-2016).
5. Steps to prepare for Tasks 3 and 4 have been initiated. On-site data collection at Hill AFB and follow-up assessments (1-week, 6-months, 12-months) are on-going.
6. 263 subjects have been enrolled since the study’s start. Since the study began, 189 participants have completed week 1 follow-ups, 89 have completed 6 month follow-ups, and 8 have completed 12 month follow-ups. Only 12 participants have withdrawn thus far. Thus far, outcome events (e.g., suicidal behaviors during follow up) have occurred at the expected rate and in line with power calculations.
7. Staff held meeting on 09-DEC-2015 regarding protocol logistics and staff changes.
8. U of U PI presented to health care providers at Hill AFB clinic’s professional staff meeting on 10-DEC-2015 to increase participant enrollment.
9. U of U PI presented to health care providers at Hill AFB CAIB meeting on 19-FEB-2016 to increase participant enrollment.
10. New research assistant (William Russell) added to Hill AFB to increase participant enrollment (04-JAN-2016).
11. Initiated new recruitment methods at Hill AFB (e.g., handing out flyers to those waiting for their appointment in the clinic) to increase participant enrollment (15-MAY-2016).

**Specific objectives:**

1. Receive Department of Army HRPO approval
2. Begin enrollment and follow-up assessments at Portsmouth Naval Medical Center, Fort Carson, and McConnell AFB.
3. Continue enrollment and follow-up assessments at Hill AFB

Objective 1 has not been completed due to the slow turnaround times of the Navy IRB and Army HRPO. Objective 2 has been delayed due to staffing changes and slow turnaround times of the Army HRPO. We received IRB approval for HRPO-requested protocol changes on 19-SEP-2016 and will be submitting these changes to HRPO for review this month. Progress on Objective 3 has been steady and continues as planned.

There are currently no major findings to report as data are still being collected.

3.3. What opportunities for training and professional development has the project provided?

Nothing to Report.

3.4. How were the results disseminated to communities of interest?

Nothing to Report.
3.5. **What do you plan to do during the next reporting period to accomplish the goals?**

<table>
<thead>
<tr>
<th>During the next reporting period we plan to complete the four objectives identified above to keep in line with the timeline proposed for tasks 3-5:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Receive Department of Army HRPO approval</td>
</tr>
<tr>
<td>2. Begin enrollment and follow-up assessments at Portsmouth Naval Medical Center, Fort Carson, and McConnell AFB.</td>
</tr>
<tr>
<td>3. Continue enrollment and follow-up assessments at Hill AFB</td>
</tr>
</tbody>
</table>

### 4. Impact

#### 4.1. What was the impact on the development of the principal discipline(s) of the project?

Nothing to Report.

#### 4.2. What was the impact on other disciplines?

Nothing to Report.

#### 4.3. What was the impact on technology transfer?

Nothing to Report.

#### 4.4. What was the impact on society beyond science and technology?

Nothing to Report.

### 5. Problems/Issues:

#### 5.1. Changes in approach and reasons for change

Due to staffing changes and challenges working with certain sites, we discontinued plans to recruit at JBPHH and Pensacola. We have partnered with three new sites, specifically Portsmouth Naval Medical Center, Fort Carson, and McConnell AFB. Site evaluators have been identified at each site. We continue to work with all involved IRBs to secure the appropriate approvals to begin data collection.

#### 5.2. Actual or anticipated problems or delays and actions or plans to resolve them

There has been administrative slow down on the part of HRPO. We have had to reaccomplish IIAs and IAIIRs several times due to inconsistencies and ambiguities within the regulatory process regarding the most appropriate paperwork to complete. This administrative issue has caused enrollment to be delayed indefinitely at Portsmouth Naval Medical Center. We have resolved these issues and hope to receive final approval from HRPO to initiate data collection at our new research sites during the next quarter of performance.

#### 5.3. Changes that had a significant impact on expenditures

Nothing to Report.

#### 5.4. Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to Report.
6. Products:

6.1. Publications, conference papers, and presentations

Nothing to Report.

6.2. Website(s) or other Internet site(s)

Nothing to Report.

6.3. Technologies or techniques

Nothing to Report.

6.4. Inventions, patent applications, and/or licenses

Nothing to Report.

6.5. Other products

Nothing to Report.

7. Participants & Other Collaborating Organizations

7.1. What individuals have worked on the project?

<table>
<thead>
<tr>
<th>Personnel</th>
<th>Role</th>
<th>Percent Effort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bryan, Craig</td>
<td>Principal Investigator</td>
<td>0.17</td>
</tr>
<tr>
<td>Allen, Michael</td>
<td>Co-Investigator</td>
<td>0.10</td>
</tr>
<tr>
<td>Clemans, Tracy</td>
<td>Co-Investigator</td>
<td>0.05</td>
</tr>
<tr>
<td>May, Alexis</td>
<td>Postdoctoral Research Coordinator</td>
<td>1.00</td>
</tr>
<tr>
<td>Harris, Julia</td>
<td>Research Manager</td>
<td>1.00</td>
</tr>
<tr>
<td>Bryan, AnnaBelle</td>
<td>Evaluator</td>
<td>0.10</td>
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<tr>
<td>Hinkson, Kent</td>
<td>Evaluator</td>
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<tr>
<td>Cable, Emily</td>
<td>Evaluator</td>
<td>0.50</td>
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<tr>
<td>Williams, Sean</td>
<td>Evaluator</td>
<td>0.50</td>
</tr>
<tr>
<td>Reynolds, Mira</td>
<td>Student research assistant</td>
<td>0.80</td>
</tr>
<tr>
<td>White, Kirsi</td>
<td>Student research assistant</td>
<td>1.00</td>
</tr>
<tr>
<td>Haddock, Leslie</td>
<td>Research assistant</td>
<td>1.00</td>
</tr>
<tr>
<td>Kawaa, Patricia</td>
<td>Research assistant</td>
<td>1.00</td>
</tr>
</tbody>
</table>

7.2. Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report.

7.3. What other organizations were involved as partners?

Nothing to Report.
Improving universal suicide prevention screening in primary care by reducing false negatives

1304600 / Universal suicide prevention screens
W81XWH-14-1-0272

PI: Craig J. Bryan, PsyD, ABPP
Org: University of Utah
Award Amount: $3,441,421

Study/Product Aim(s)

• Objective: To improve the accurate detection of individuals at risk of suicidal behavior by assessing chronic as well as acute suicide risk.

• Aim: To reduce current high rates of false negatives resulting from universal suicide prevention screening in military primary care clinics

Approach

Patients at military primary care clinics (n > 5000) will complete several self-report measures, including the SCS and current screening tools used in the military (i.e., PHQ2 and PHQ9). Follow-up assessments will be conducted at 6 and 12 months to determine the incidence of suicide attempts. Analyses will determine which screening items best predict suicide attempts in the full sample and in patient subgroups.

Accomplishments: In FY15-16, 244 participants were enrolled at Hill Air Force Base. 176 completed 1 week follow ups and 88 completed 6 month follow ups, with a 74% retention rate for 1 week calls and a 71% retention for 6 month calls. New research sites have been secured (McConnell Air Force Base, Portsmouth Naval Medical Center, Fort Carson).

Timeline and Cost

<table>
<thead>
<tr>
<th>Activities</th>
<th>FY 14</th>
<th>FY 15</th>
<th>FY 16</th>
<th>FY 17</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB approvals, database construction, staff hiring &amp; training</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participant enrollment, completion of baseline surveys, follow-up interview</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Data analyses, manuscript and report writing, dissemination of results</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Estimated Budget ($K): $896, $824, $848, $873

Updated: 31 August 2016

Goals/Milestones

CY14 Goal – IRB approval
☑ Obtain IRB approval

CY15 Goals – Initiate data collection
☑ Hire research staff
☑ Begin participant enrollment
☑ Begin 6-month follow-up assessments

CY16 Goal – Continue participant enrollment
☑ Continue enrollment
☑ Continue 6 and 12-month follow-up assessments

CY17 Goal – Conclude follow-up assessments
☐ Conclude follow-up assessments
☐ Analyze data and disseminate results

Comments/Challenges/Issues/Concerns

• Delays in recruitment due to site staff and IRB staff turnover.

Budget Expenditure to Date

Projected Expenditure: $1,900,446.00
Actual Expenditure: $1,012,767.02